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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO THE COMPLAINT

Plaintiff/Counterclaim-Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims ("Counterclaims") of Defendant/Counterclaim-Plaintiff Hikma Pharmaceuticals USA Inc., ("Hikma" or "Defendant") (ECF No. 71; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in Hikma's Counterclaims except for those specifically admitted

below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

THE PARTIES

1. On information and belief and as it pled in its Complaint, ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

2. Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: On the basis of Hikma's answer in the Counterclaims to Paragraph 3 in the Counterclaims, admitted.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 3 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Hikma purports to bring the Counterclaims under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI specifically denies that the Counterclaims have merit or that Hikma is entitled to any relief on its Counterclaims.

4. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed suit.

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction in this judicial district for the purposes of this action only.

5. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only.

BACKGROUND

6. Upon information and belief, ARI holds approved New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/1 mL), (2) eq. 60 mcg Selenium/1 mL (eq. 60 mcg Selenium/1 mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/1 mL)).

ANSWER: Admitted.

7. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, admitted.

8. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, admitted.

9. U.S. Patent 11,998,565 ("the '565 patent"), entitled "Trace element compositions, methods of making and use," issued on June 4, 2024.

ANSWER: Admitted.

10. Upon information and belief based upon the United States Patent Office's assignment database, ARI is the assignee of the '565 patent.

ANSWER: Admitted.

11. U.S. Patent 12,150,957 ("the '957 patent"), entitled "Trace element compositions, methods of making and use," issued on November 6, 2024.

ANSWER: Admitted.

12. Upon information and belief based upon the United States Patent Office's assignment database, ARI is the assignee of the '957 patent.

ANSWER: Admitted.

13. Hikma submitted Abbreviated New Drug Application ("ANDA") No. 217680 ("the ANDA") to obtain FDA approval to market generic versions of ARI's Selenious Acid Products ("the ANDA Products") prior to issuance of either the '565 or '957 patents. At the time Hikma filed its ANDA, there were no patents listed in the Orange Book for the Selenious Acid products.

ANSWER: ARI admits that Hikma notified ARI that Hikma submitted ANDA No. 217680 to market a generic version of ARI's Selenious Acid products. ARI otherwise lacks sufficient knowledge and information to form a belief as to the truth of the allegations of Paragraph 13 as pled and denies them on that basis.

14. Upon information and belief, after its issuance, Counterclaim Defendant/Plaintiff caused the '565 patent to be listed in the Orange Book as a drug product patent for NDA No. 209379.

ANSWER: Admitted.

15. Hikma amended its ANDA to add a Paragraph IV Certification to the '565 patent.

ANSWER: Paragraph 15 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Hikma notified ARI that ANDA No. 217680 includes a Paragraph IV Certification with respect to the '565 patent. ARI denies the remaining allegations in Paragraph 15.

16. Pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendant/Plaintiff by letter (the "Hikma Notice Letter") that Hikma had submitted a Paragraph IV Certification for its ANDA with respect to the '565 patent. The Hikma Notice Letter, which is

incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the '565 patent are invalid, not infringed, and/or unenforceable.

ANSWER: Paragraph 16 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Hikma's Notice Letter informed ARI that ANDA No. 217680 includes a Paragraph IV Certification with respect to the '565 patent. ARI further admits that Hikma's Notice Letter contained arguments and/or positions that the '565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies the remaining allegations in Paragraph 16.

17. On July 16, 2024, Counterclaim Defendant/Plaintiff filed *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, C.A. No. 24-7803 (D.N.J.) (the "Related Action") alleging infringement of the '565 patent.

ANSWER: Admitted.

18. Upon information and belief, after its issuance, Counterclaim Defendant/Plaintiff caused the '957 patent to be listed in the Orange Book as a drug product patent for NDA No. 209379.

ANSWER: Admitted.

19. On December 13, 2024, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the '957 patent.

ANSWER: Admitted.

COUNT I

(Declaratory Judgment of Invalidity or Unenforceability of the '957 Patent)

20. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 16 of its Counterclaims as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

21. Counterclaim Defendant/Plaintiff alleges ownership of the ’957 patent and has brought claims against Hikma alleging infringement of the ’957 patent.

ANSWER: Admitted.

22. One or more claims of the ’957 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

ANSWER: Denied.

23. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma’s ANDA and/or the commercial marketing of Hikma’s ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’957 patent.

ANSWER: Paragraph 23 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is an actual, substantial, continuing, and justiciable case and controversy between ARI and Hikma regarding Hikma’s infringement of the ’957 patent. ARI specifically denies that there is an actual, substantial, and continuing justiciable case and controversy between ARI and Hikma regarding invalidity or unenforceability of the ’957 patent. ARI specifically denies that these Counterclaims have merit or that Hikma is entitled to any relief on its Counterclaims.

24. Hikma is entitled to a declaration that all claims of the ’957 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

ANSWER: Denied.

COUNT II

(Declaratory Judgment of Non-Infringement of the ’957 Patent)

25. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

26. Counterclaim Defendant/Plaintiff alleges ownership of the ’957 patent and has brought claims against Hikma alleging infringement of the ’957 patent.

ANSWER: Admitted.

27. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma’s ANDA and/or the commercial marketing of Hikma’s ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the ’957 patent.

ANSWER: Paragraph 27 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is an actual, substantial, continuing, and justiciable case and controversy between ARI and Hikma regarding Hikma’s infringement of the ’957 patent. ARI specifically denies that the Counterclaims have merit or that Hikma is entitled to any relief on its Counterclaims.

28. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’957 patent and is not liable for such infringement.

ANSWER: Denied.

29. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma’s ANDA Product would not infringe any valid or enforceable claim of the ’957 patent.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Hikma is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (a)–(f) of Counterclaimant Hikma’s Prayer for Relief.

Each averment and/or allegation contained in Hikma’s Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Hikma's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant Hikma Pharmaceuticals USA Inc.'s Answer, Separate Defenses, and Counterclaims to the Complaint was served by ECF on all counsel of record and electronic mail on all counsel of record for Hikma.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier